

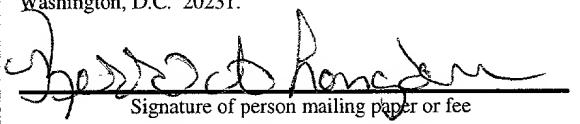
Atty. Dkt. 4002-2533

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: )  
Charles L. Branch et al. )  
Serial No. )  
Filed Herewith )  
INTERBODY FUSION GRAFTS )  
AND INSTRUMENTATION )

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Signature of person mailing paper or fee

**PRELIMINARY AMENDMENT**

Hon. Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Please consider this Preliminary Amendment in the above-captioned patent application prior to examination. A marked-up version of each amended paragraph is provided on a separate sheet attached to this Preliminary Amendment and entitled, "Version with Markings to Show Changes Made."

A Petition to Make Special and an Information Disclosure Statement are also filed concurrent with this Preliminary Amendment.

It is believed no fee is due; however, please charge any fees that may be due or credit any overpayment to Deposit Account No. 23-3030, but not to include payment of any issue fee.

**AMENDMENTS**

In the Specification:

On page 1, immediately after the title, please add the following paragraph:

--CROSS-REFERENCE TO RELATED APPLICATION

The present application claims the benefit of United States Application Serial No. 09/698,623, filed October 27, 2000, and United States Application Serial No. 09/181,353, filed on October 28, 1998, now U.S. Patent No. 6,174,311, and to U.S. Patent Application Serial No. 09/722,205, filed November 25, 2000, which in turn claims priority under 35 U.S.C. §119 to PCT Application Serial No. US98/17769, filed August 27, 1988, which are hereby incorporated by reference in their entirety.--

Please replace the paragraph on page 17, lines 19-24 with the following paragraph:

--The gripping head 152 includes at least one implant engaging structure. Preferably gripping head includes taper ends 166 and 168 that engage in corresponding recesses in the implant. The projections are provided to control lateral and vertical motion as the implant is impacted into the intervertebral space. Optimally, gripping head also includes a surface that can be used to impact or drive the implant in the preformed cavity.--

Please see page 17, lines 28-31 for support for the amendment.

Please replace the paragraph on page 27, lines 15-24 with the following paragraph:

--Additional cutting instruments are provided for use with the present invention. For example, shaver 280 illustrated in FIGS. 26 and 26a is provided with a cutting head 286, shaft 284, and handle 282. Handle 282 includes a receptacle 283 or attachment of a slap hammer. Cutting head 286 includes upper shaving blade 288 and lower shaving blade 290 provided between first arm 287 and second arm 289. Upper and lower shaving blade 288 and 290 are orthogonal to first and second arms 287 and 289 such that when the upper or lower shaving blade 288 or 290 or both are raked across tissue surfaces, the blades cut or scrape away a portion of tissue surface. Cutting head 286 also includes a series of index markings 294 to determine the depth of the scraper head in tissue.--

Please see FIG. 26a for support.

Please replace the paragraph on page 27, line 25, through page 28, line 10, with the following paragraph:

--Round scraper illustrated in FIGS. 32-32f is provided for use with the present invention. Round scraper 390 includes shaft 402 and scraper head 392. Shaft 402 defines a longitudinal axis 391. Scraper head 392 includes a first arm 393 and a second arm 395. Shaft 402 includes a tapered neck 403. First arm 393 and second arm 395 define a cavity 398 for receipt of cutting debris. Attached to first and second arm 393 and 395 are rounded scraper edges 394 and 396. First arm 393 and second arm 395 are attached to curved tip 404. Rounded scraper edges 394 and 396 are backward-facing cutting edges, which can cut bone or other tissue as the round scraper 390 is withdrawn from the disc space. Round scraper edges 394 and 396 are provided to allow simultaneous cutting on opposing surfaces of adjacent vertebral bodies. First arm 393 includes an upper surface 397 and a lower surface 400. Upper surface 397 and lower surface 400 are substantially flat. Second arm 395 includes similar structures. Upper surface 397 and/or lower surface 400 allow for controlled scraping of the disc space by contacting either the upper or lower vertebral body. Furthermore, the flat upper and lower surfaces 397 and 400 and tapered neck 403 are adapted to provide enhanced viewing of the disc space. It is important to be able to view the disc space while positioning the round scraper 390 in the disc space to remove bony tissue. Round scraper 390 is provided for preparing a bottom of the preformed cavity for proper seating of implants as depicted in the present invention.--

Please see the sentence bridging lines 30 and 31 on page 27 for support.

Please replace the paragraph on page 28, lines 18-30 with the following paragraph:

--As shown in FIG. 34, there is also provided in accordance with the present invention rotatable cutter 430. Cutter 430 includes handle 432, shaft 434, and cutter head 436. Cutter head 436 includes first cutting arm 437 and second arm 439. First cutting arm 437 and second cutting arm 439 are spaced apart and define a cavity 448 therebetween for receipt of cutting debris. First cutting arm 437 includes at least two cutting blades. For example, FIG. 34a depicts cutting arm 437 having a first cutting blade 438 and opposite second cutting blade 440. First and second cutting

blades extend longitudinally and are positioned to lie parallel to the longitudinal axis of rotatable cutter 430. Similarly, second cutting arm 439 is provided with a first cutting blade 442 and a second cutting blade 443. Rotatable cutter 430 is provided for use in a disc space to cut adjacent endplates of adjacent vertebrae by twisting the cutter. As with other instruments, the cutting head includes index marks 441 to indicate the depth the rotatable cutter is inserted into tissue.

The reference numeral 440 has already been assigned to the second cutting blade; please see page 28, line 24.

In the Drawings:

Please amend FIG. 11 by changing the reference number “85” to --15--, as shown in red ink on the accompanying drawing sheets appended to this response.

Please amend Figure 13 by adding reference numbers 110, 111, 120 and 132 and substituting reference number --129-- for number “121” as shown in red ink on the accompanying drawing sheet appended to this Response.

Please amend Figure 14 by adding reference numbers 120, 122, 128 and 132 as shown in red ink on the accompanying drawing sheet appended to this Response.

Please amend Figure 15 by adding the reference number 132 as shown in red ink on the accompanying drawing sheet appended to this Response.

Please amend FIG. 18b by adding the reference numeral on --152-- as shown in red ink on the accompanying drawing sheet appended to this response.

Please amend FIG. 19 by changing the reference numeral “10” to --110-- and adding the reference numerals --152-- and --157-- as shown in red ink on the accompanying drawing sheet appended to this response.

Please amend FIG. 20a by adding the reference numerals --152-- and --157-- as shown in red ink on the accompanying drawing sheet appended to this response.

Please amend FIG. 22 by changing the lead line for reference numeral “216” as shown in red ink on the accompanying drawing sheet appended to this response.

Please amend FIG. 25b by changing adding the reference numeral --296-- and by changing the reference numeral “272” to --273-- as shown in red ink on the accompanying drawing sheet appended to this response.

Please amend FIG. 34a by changing the reference numeral “244” to --441-- as shown in red ink on the accompanying drawing sheet appended to this response.

Please amend FIG. 44c by renaming the figure as FIG. 46a.

Substitute drawing sheets incorporating the above-proposed amendments are also appended to this Response.

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In the Claims:

Please add the following new claims 63-88, as follows:

- 63. A spinal fusion implant, comprising:  
an elongate bone portion having a generally rectangular cross-section and defining a longitudinal axis, said bone portion comprising:  
an first bone engaging surface;  
a second bone engaging surface; and  
a first sidewall extending between said first and second bone engaging surfaces, wherein the first sidewall comprises a concave surface.
64. The implant of claim 63 wherein the concave surface is arcuate.
65. The implant of claim 63, wherein said bone portion is formed from a donor bone segment having at least a portion of a medullary canal and the concave surface defines a portion derived from the medullary canal.
66. The implant of claim 63 comprising a second sidewall having a convex portion.
67. The implant of claim 63 comprising a second sidewall having a substantially planar portion.
68. The implant of claim 63 comprising a second sidewall positioned to lie substantially parallel to the first sidewall.
69. The implant of claim 63 wherein the first bone engaging surface is substantially crescent shaped.

70. The implant of claim 63, wherein at least one of the first and second bone engaging surfaces include ridges or teeth.
71. The implant of claim 63 wherein the first bone engaging surface and the second bone engaging surface are substantially planar.
72. The implant of claim 63 wherein the first bone engaging surface and the second bone engaging surface are separated by a first height adjacent to a first end and by a second height adjacent to an opposite, second end, wherein said first height is greater than the second height.
73. The implant of claim 63 wherein the first bone engaging surface and the second bone engaging surface are adapted to matingly conform to opposing endplates of adjacent vertebral bodies.
74. The implant of claim 63 wherein the first sidewall comprises a first substantially planar surface adjacent the first portion.
75. The implant of claim 63 wherein the first sidewall comprises a first substantially planar surface adjacent a first end and a second substantially planar surface adjacent a second end.
76. The implant of claim 63 comprising a first endwall positioned between the first and second bone engaging surfaces, wherein the first endwall is adapted to engage an implant holder.
77. The implant of claim 76 wherein the first endwall comprises a recess or a projection to engage an implant holder.

78. The implant of claim 76 wherein the first endwall comprises a recess extending to the first portion.

79. The implant of claim 76 wherein the recess defines a bore extending substantially parallel to the longitudinal axis.

80. The implant of claim 79 wherein the bore is threaded.

81. The implant of claim 76 wherein the recess defines a groove extending substantially parallel to the longitudinal axis.

82. A spinal fusion implant, comprising:  
an elongate bone portion defining a longitudinal axis and comprising:  
a first sidewall comprising a concave surface;  
a second, opposite sidewall comprising a convex surface;  
a first bone engaging surface positioned between the first and second sidewalls; and  
a second bone engaging surface opposite the first bone engaging surface, wherein at least one of the first or second bone engaging surfaces comprises ridges or teeth.

83. The implant of claim 82 comprising a tool attachment end positioned between the first and second bone engaging surfaces, said tool attachment end comprising a recess extending substantially parallel to the longitudinal axis from the tool attachment end to the convex surface.

84. A system for spinal fusion of adjacent vertebrae, said system comprising a pair of spinal implants, said spinal implants comprising an elongate bone portion having a generally rectangular cross-section; a first bone engaging surface; a second, opposite bone engaging surface; and a first sidewall extending between said first and second bone engaging surfaces, said first sidewall comprising a concave portion, said pair of implants are positioned in an intervertebral space whereby the concave portions define a chamber.

85. The system of claim 84 wherein the chamber comprises an osteogenic material.

86. The system of claim 84 wherein the implants do not contact each other.

87. The system of claim 84 wherein the implants are positioned to lie at an angle oblique to each other.

88. The system of claim 84 wherein each of the implants comprise a tool attachment end positioned posteriorly in the intervertebral space.

Please cancel claims 5-62, without prejudice.

## REMARKS

Entry of this Preliminary Amendment prior to the examination of this application is respectfully requested. Applicants have cancelled claims 5-62 and reserve the right to pursue the subject matter of these claims in a continuing application.

Applicants have also submitted new claims 63-88, and the filing fee is based upon the number of claims after entry of this Preliminary Amendment.

Drawing corrections are proposed with respect to reference numbers on the drawings and to render the drawings in full compliance with 37 C.F.R. §1.83.

Applicants respectfully request consideration of this application and Preliminary Amendment, and passage of this application to allowance.

Respectfully submitted,

By:

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Woodard, Emhardt, Naughton

Morarty & McNett  
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(317) 634-3456

Version with Markings to Show Changes Made

In the Specification

A paragraph has been added on page 1, after the title.

The paragraph beginning on page 17, line 19, has been amended as follows:

The gripping head 152 includes at least one implant engaging structure. Preferably gripping head includes [projections] taper ends 166 and 168 that engage in corresponding recesses in the implant. The projections are provided to control lateral and vertical motion as the implant is impacted into the intervertebral space. Optimally, gripping head also includes a surface that can be used to impact or drive the implant in the preformed cavity.

The paragraph beginning on page 27, line 15, has been amended as follows:

Additional cutting instruments are provided for use with the present invention. For example, shaver 280 illustrated in [FIG.] FIGS. 26 and 26a is provided with a cutting head 286, shaft 284, and handle 282. Handle 282 includes a receptacle 283 or attachment of a slap hammer. Cutting head 286 includes upper shaving blade 288 and lower shaving blade 290 provided between first arm 287 and second arm 289. Upper and lower shaving blade 288 and 290 are orthogonal to first and second arms 287 and 289 such that when the upper or lower shaving blade 288 or 290 or both are raked across tissue surfaces, the blades cut or scrape away a portion of tissue surface. Cutting head 286 also includes a series of index markings 294 to determine the depth of the scraper head in tissue.

The paragraph beginning on page 27, line 25, through page 28, line 10, has been amended as follows:

--Round scraper illustrated in FIGS. 32-32f is provided for use with the present invention.

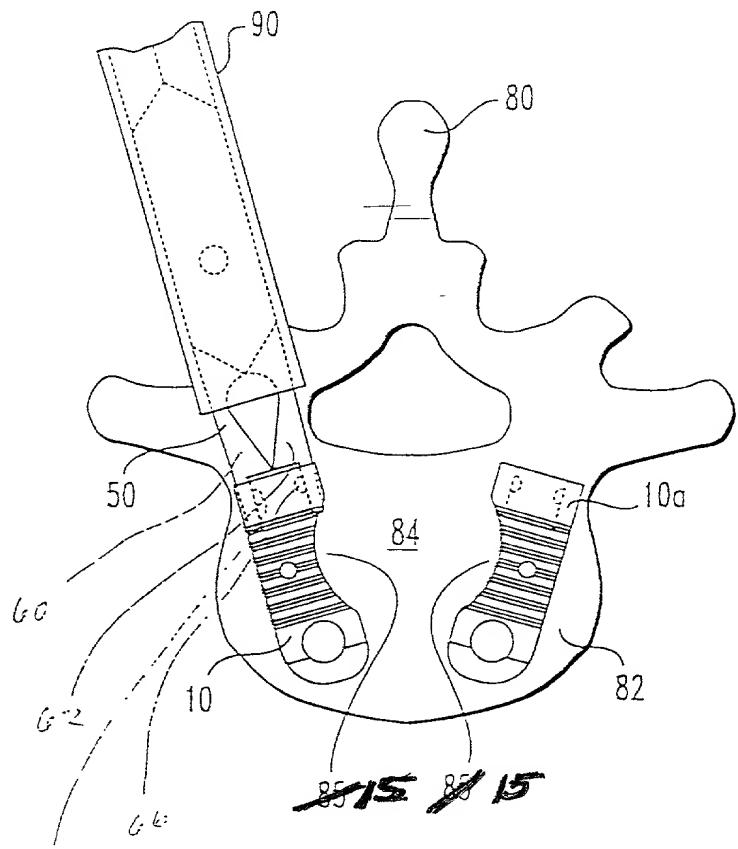
Round scraper 390 includes shaft 402 and scraper head 392. Shaft 402 defines a longitudinal axis 391. Scraper head 392 includes a first arm 393 and a second arm 395. Shaft 402 includes a tapered neck 403. First arm 393 and second arm 395 define a cavity 398 for receipt of cutting debris. Attached to first and second arm 393 and 395 are rounded scraper edges 394 and 396. First arm 393 and second [are] arm 395 are attached to curved tip 404. Rounded scraper edges 394 and 396 are backward-facing cutting edges, which can cut bone or other tissue as the round scraper 390 is withdrawn from the disc space. Round scraper edges 394 and 396 are provided to allow simultaneous cutting on opposing surfaces of adjacent vertebral bodies. First arm 393 includes an upper surface 397 and a lower surface 400. Upper surface 397 and lower surface 400 are substantially flat. Second arm 395 includes similar structures. Upper surface 397 and/or lower surface 400 allow for controlled scaping of the disc space by contacting either the upper or lower vertebral body. Furthermore, the flat upper and lower surfaces 397 and 400 and tapered neck 403 are adapted to provide enhanced viewing of the disc space. It is important to be able to view the disc space while positioning the round scraper 390 in the disc space to remove bony tissue. Round scraper 390 is provided for preparing a bottom of the preformed cavity for proper seating of implants as depicted in the present invention.

The paragraph beginning on page 27, line 18, has been amended as follows:

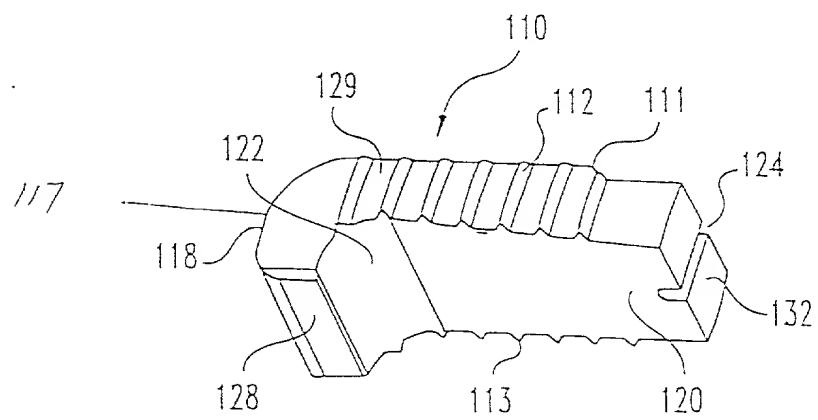
As shown in FIG. 34, there is also provided in accordance with the present invention rotatable cutter 430. Cutter 430 includes handle 432, shaft 434, and cutter head 436. Cutter head 436 includes first cutting arm 437 and second arm 439. First cutting arm 437 and second cutting arm 439 are spaced apart and define a cavity 448 therebetween for receipt of cutting debris. First cutting arm 437 includes at least two cutting blades. For example, FIG. 34a depicts cutting arm 437 having a first cutting blade 438 and opposite second cutting blade 440. First and second cutting blades extend longitudinally and are positioned to lie parallel to the longitudinal axis of rotatable cutter 430. Similarly, second cutting arm 439 is provided with a first cutting blade 442 and a second cutting blade 443. Rotatable cutter 430 is provided for use in a disc space to cut adjacent endplates

of adjacent vertebrae by a twisting the cutter. As with other instruments, the cutting head includes index marks [440] 441 to indicate the depth the rotatable cutter is inserted into tissue.

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**Fig. 11**



**Fig. 12**

100 101 102 103 104 105 106 107 108 109

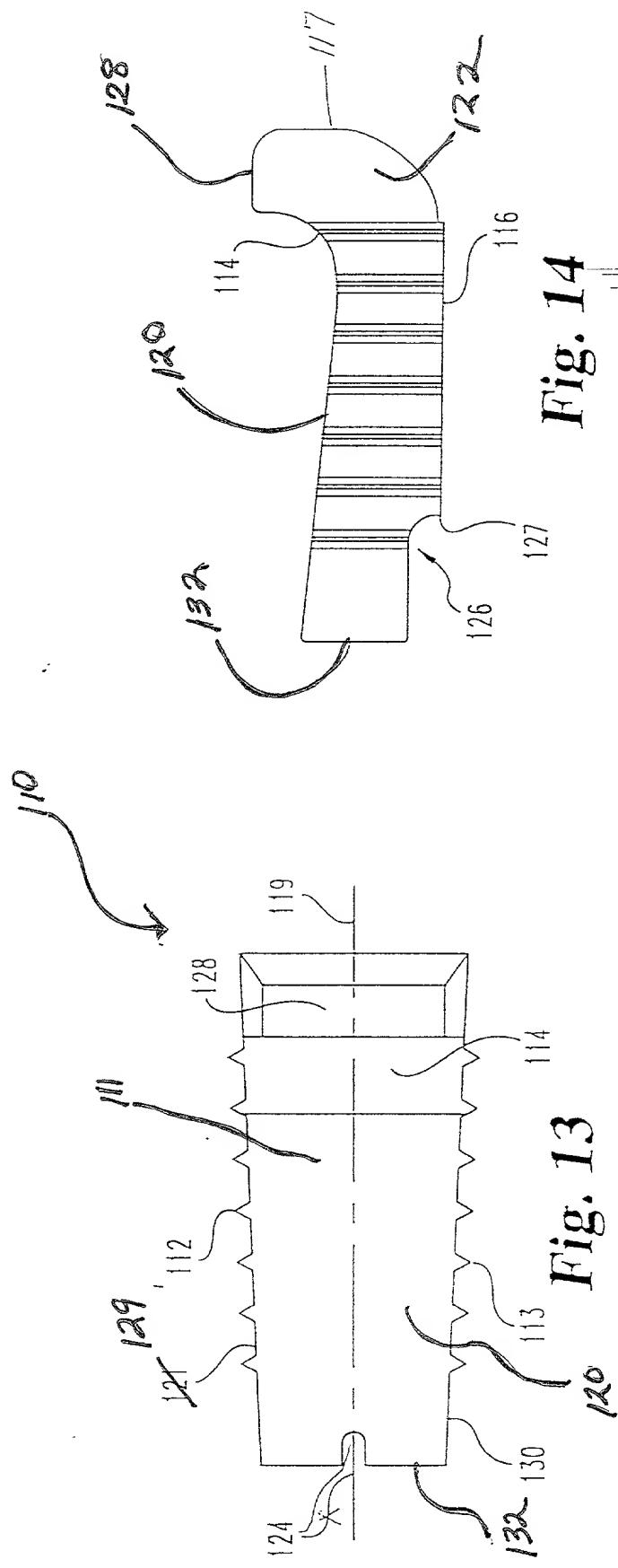


Fig. 14

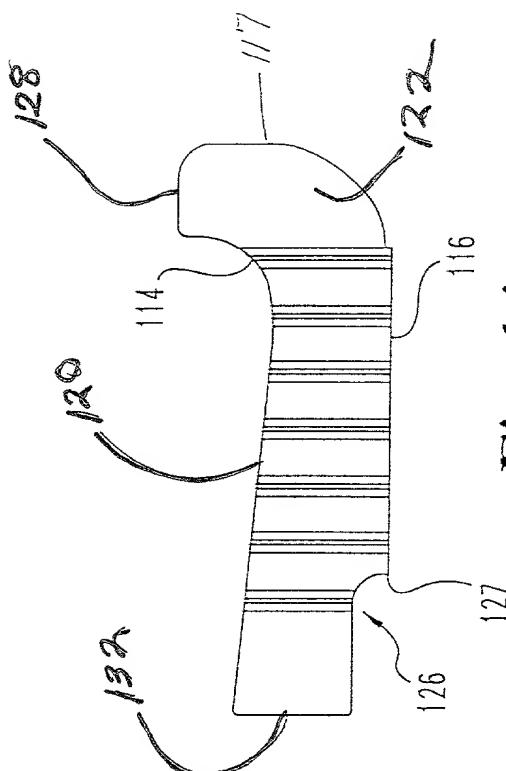


Fig. 15

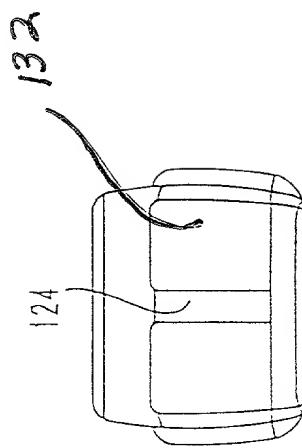


Fig. 16

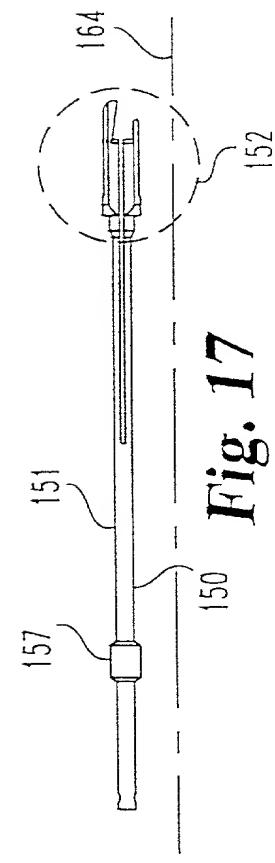


Fig. 17

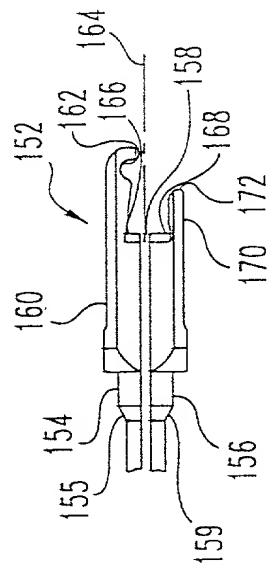


Fig. 17a

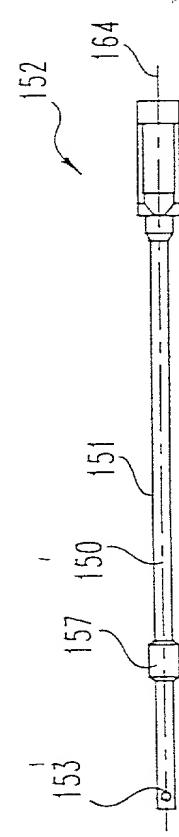


Fig. 18

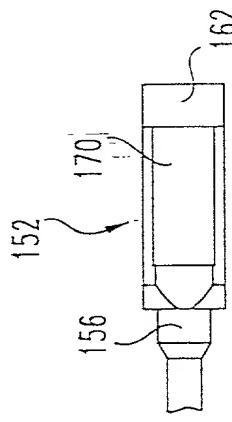


Fig. 18a

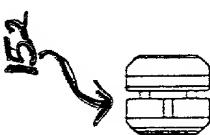


Fig. 18b

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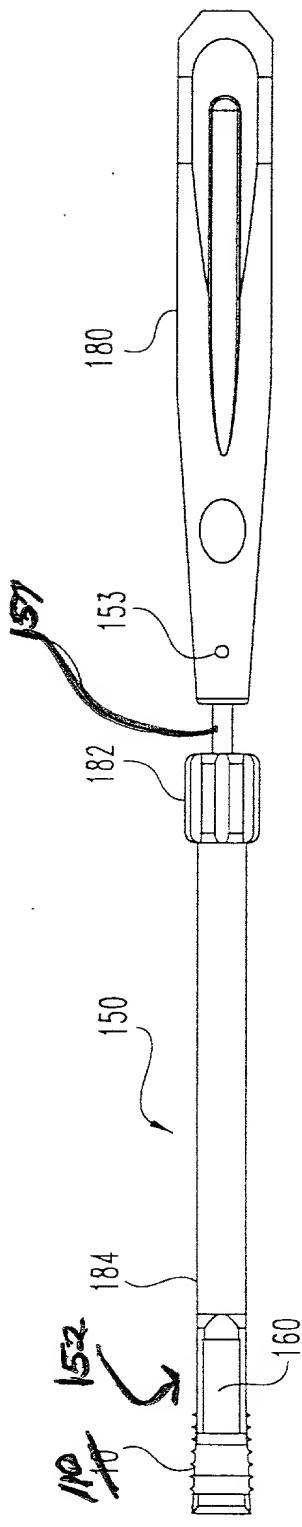


Fig. 19

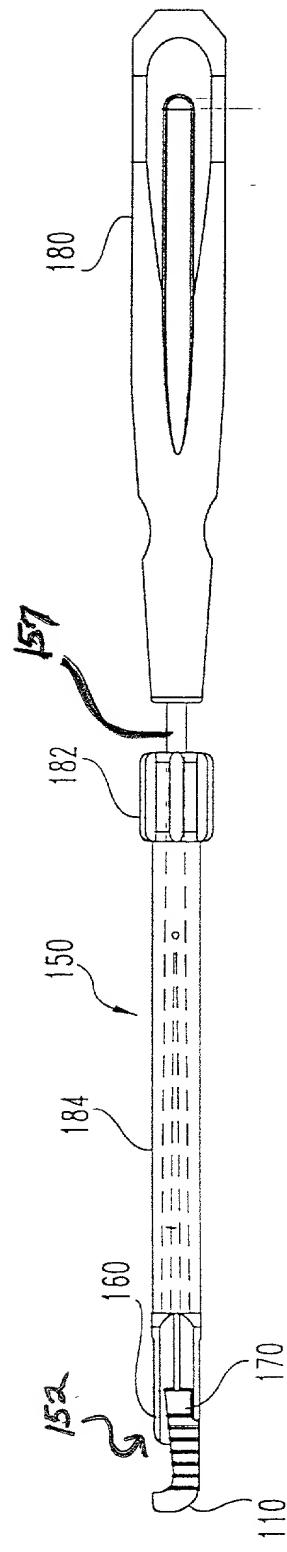


Fig. 20a

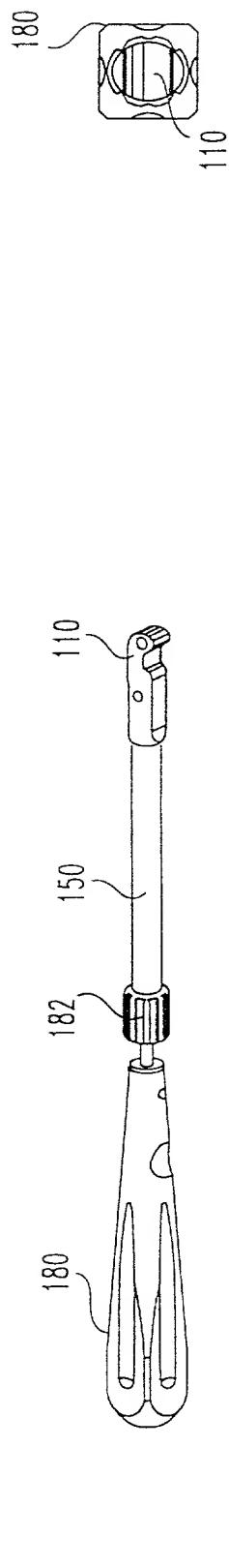
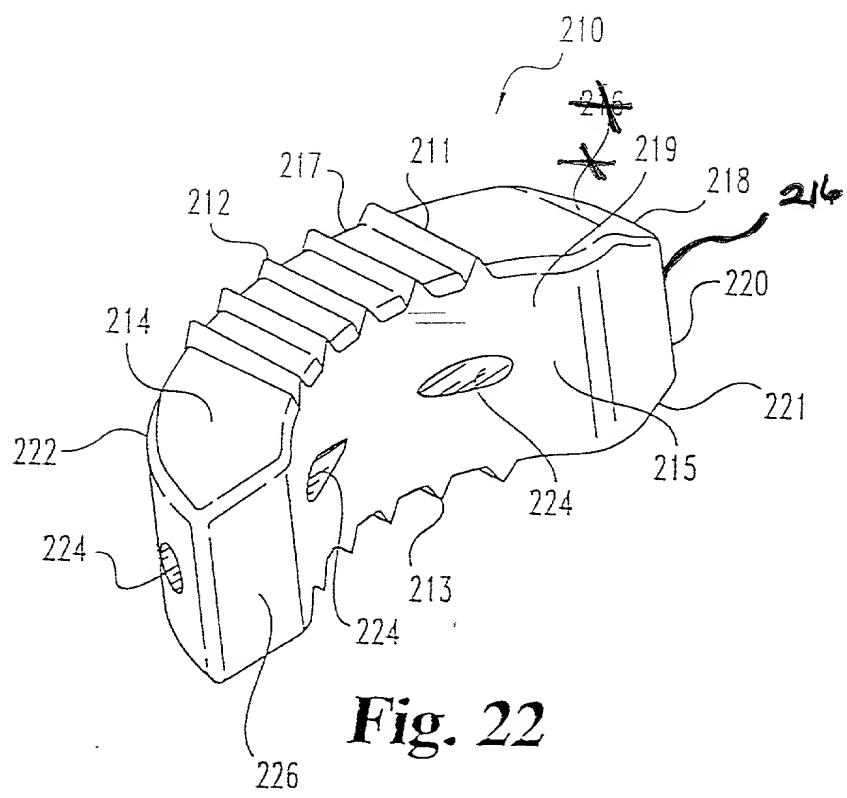
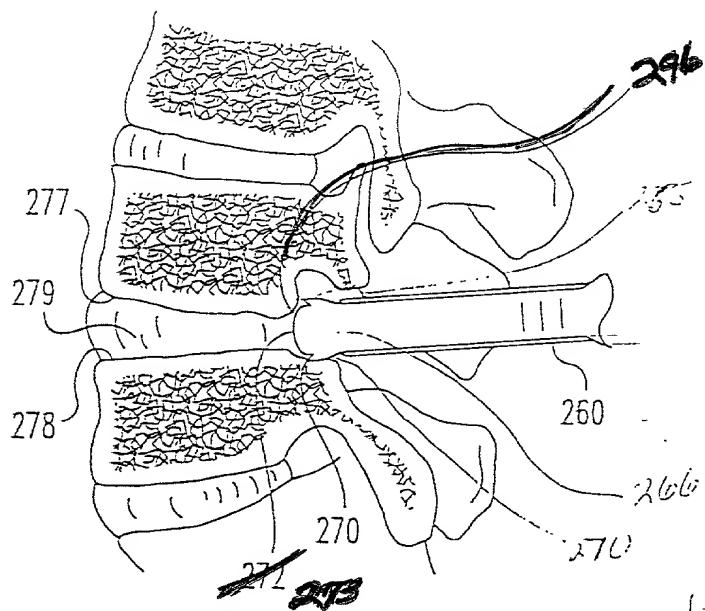


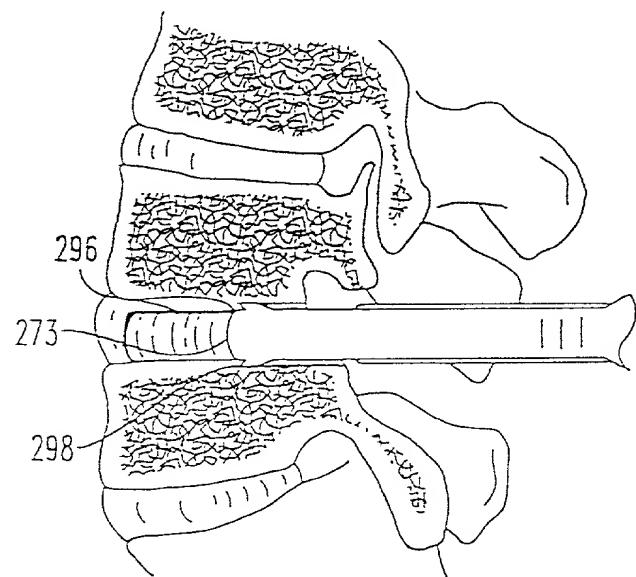
Fig. 20b  
Fig. 21



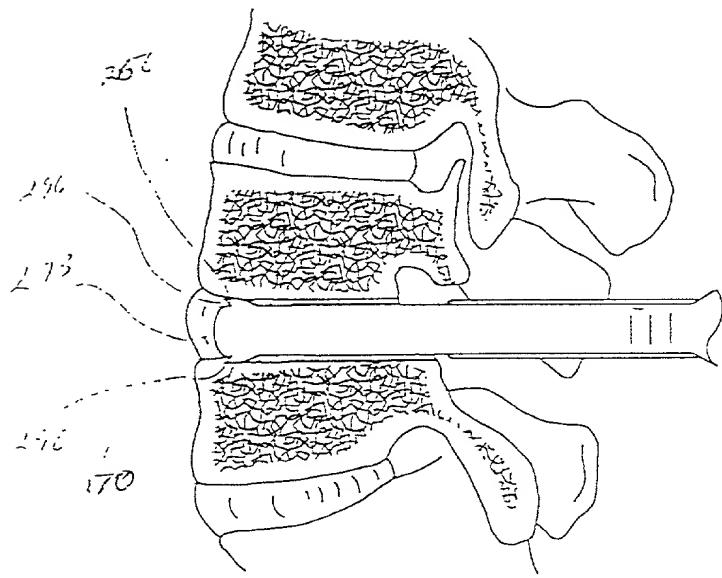
**Fig. 22**



**Fig. 25b**



**Fig. 25c**



**Fig. 25d**

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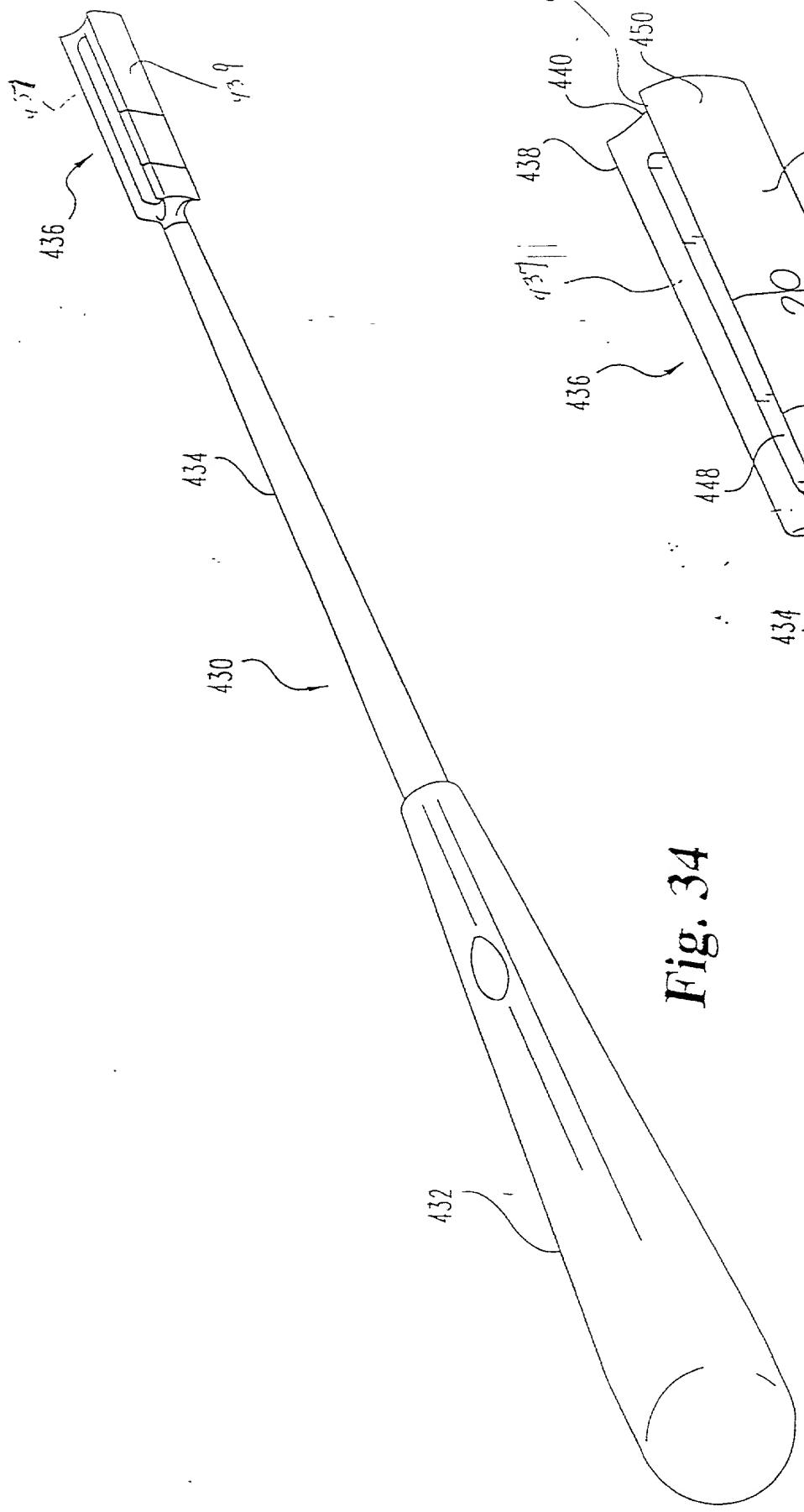


Fig. 34

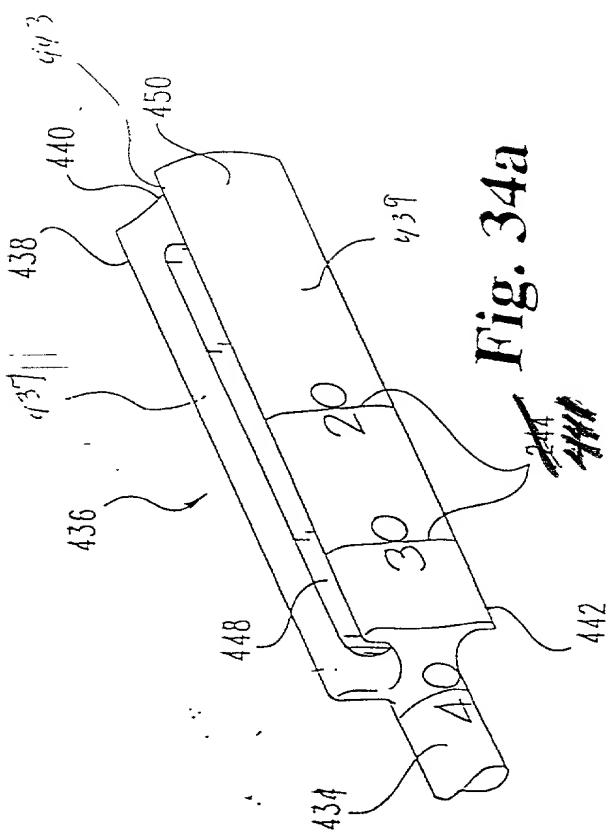


Fig. 34a

PATENT DRAWINGS

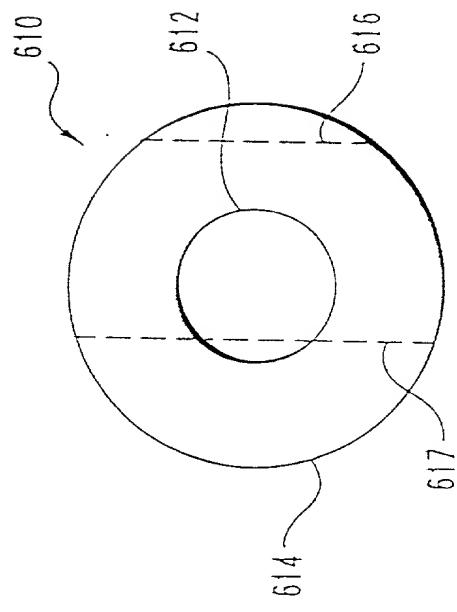


Fig. 44a

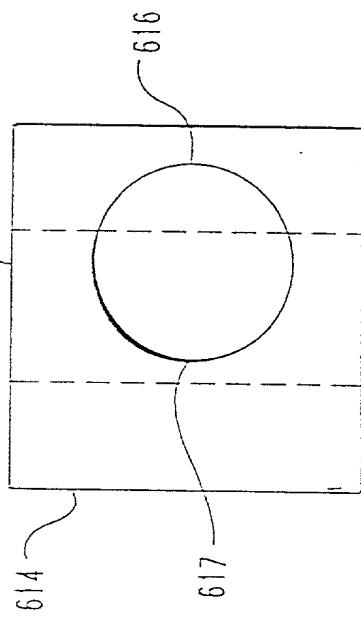
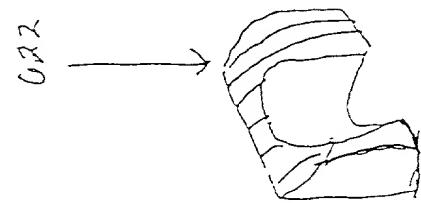


Fig. 44b

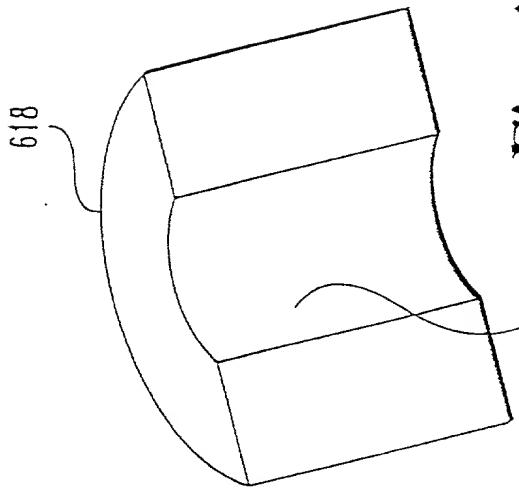


Fig. 46

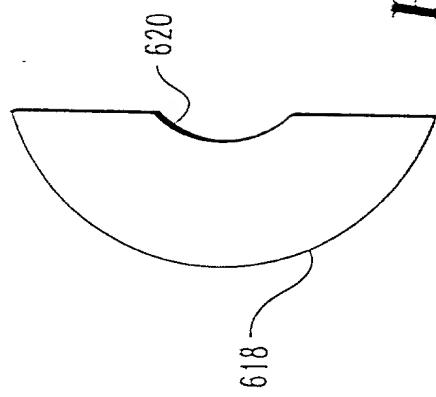


Fig. 45